

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT:	ROZIER <i>et al.</i>	)	ATTORNEY DOCKET:	04308057
		)		
SERIAL NO.:	10/501,604	)	GROUP ART UNIT:	3772
		)		
FILING DATE:	October 28, 2004	)	EXAMINER:	JACKSON, Brandon Lee
		)		
TITLE:	SITE GUARD FOR INTRAVENOUS SITES AND OTHER SENSITIVE AREAS			
		)		
DATE:	November 12, 2008	)	CUSTOMER NO.:	26565
		)		

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF LISA M. VALLINO UNDER 37 C.F.R. § 1.131**

I, Lisa M. Vallino, declare and state as follows:

1. I am one of the inventors of the subject matter provided in the above-captioned patent application, and one of the co-founders of I.V. House, Inc., which is the assignee of the above-captioned application. I have personal knowledge of the facts stated herein.
2. The above-captioned patent application discloses and claims, among other things, a site guard for intravenous sites and other sensitive areas that fastens to a patient without having to place adhesive tape on the skin of the patient.
3. I have reviewed the Shesol patent, U.S. Patent No. 6,257,240 (the '240 patent), having a filing date of June 5, 2000.
4. In 1992, I conceived of a site guard having the shape of a U-Shaped domed cup to protect intravenous sites and other sensitive areas ("I.V. House Site Guard"). This product is covered by the claims of U.S. Patent No. 5,167,240.

5. As early as 1993, Betty Rozier ("Ms. Rozier"), my mother and co-founder of I.V. House, Inc. and I exhibited the I.V. House Site Guard product at various conferences, during which time we received interest in our product from nurses who work exclusively with geriatric patients. We became concerned that the use of an I.V. House Site Guard that is secured with adhesive tape would not be beneficial to geriatric patients due to the harm that the adhesive tape can cause to their fragile skin. Because of such interest from the nurses, and the problem we had identified, we determined we needed to develop a similar site guard that could be secured to a patient without the use of any adhesive tape.

6. Between 1993 and 1999, Ms. Rozier and I conceived of new variations for the I.V. House Site Guard, including a site guard that could be secured to a patient without the use of any adhesives on a patient's skin.

7. During this same time period, we at all times continuously and diligently worked to achieve actual reduction to practice of our inventive concept for an adhesive-free site guard by, among other efforts, experimenting with various designs, techniques, concept prototypes, and materials so as to achieve an actual working product having all the properties required of our inventive concept.

8. At least as of January 8, 2000, following several years of continuous and diligent efforts to achieve actual reduction to practice of our invention concept, we created several hand-drawn sheets of drawings detailing the various design embodiments of our invention concept. Each of the dated, hand-drawn, drawings is attached hereto as Exhibit A. Accordingly, at the very latest, we achieved reduction to practice of our inventive concept on January 8, 2000, if not significantly earlier.

9. In addition, we created physical prototypes of several of the inventive embodiments that were depicted in the drawings dated January 8, 2000 as well as prototypes of embodiments that were not included in the drawings of January 8, 2000. Ms. Rozier and I created these prototypes for the purposes of physical experimentation, proof of concept, and actual reduction to practice.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Lisa M. Vallino

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L i s a V a l l i n o

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D a t e

# **EXHIBIT A**

1-8-2000

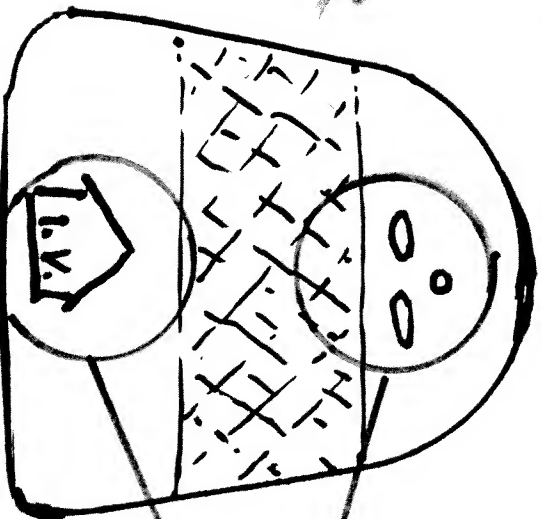
FIG 1

DRAWINGS NOT TO SCALE  
LARGE SIZE I.V. HOUSE TACK. USED



INDICATES  
VELCRO  
HOOK  
FASTENER

HADED AREAS  
INDICATE TAPELESS  
DRESSING

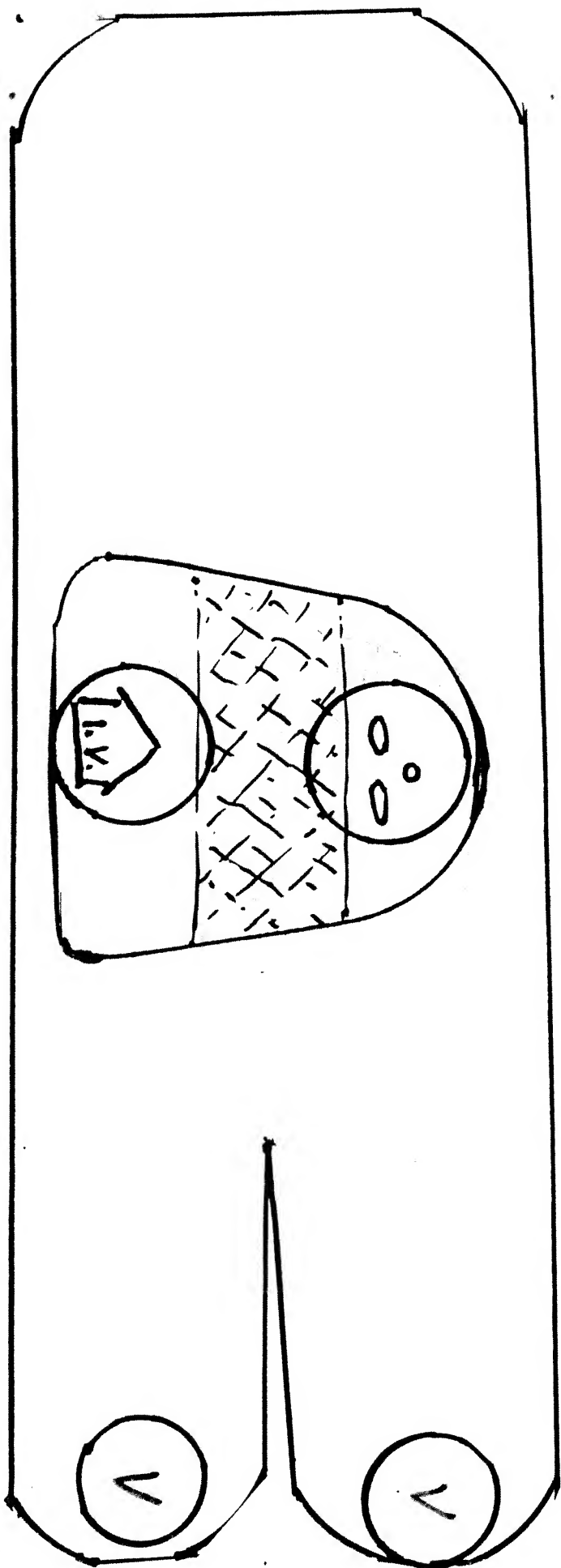


INDICATE 2  
CIRCULAR  
HOLES INTENDED

FOR VENTILATION  
AND I.V. HOUSE  
TO BE VISIBLE  
WHEN TAPELESS  
DRESSING COVERS  
AN I.V. HOUSE.

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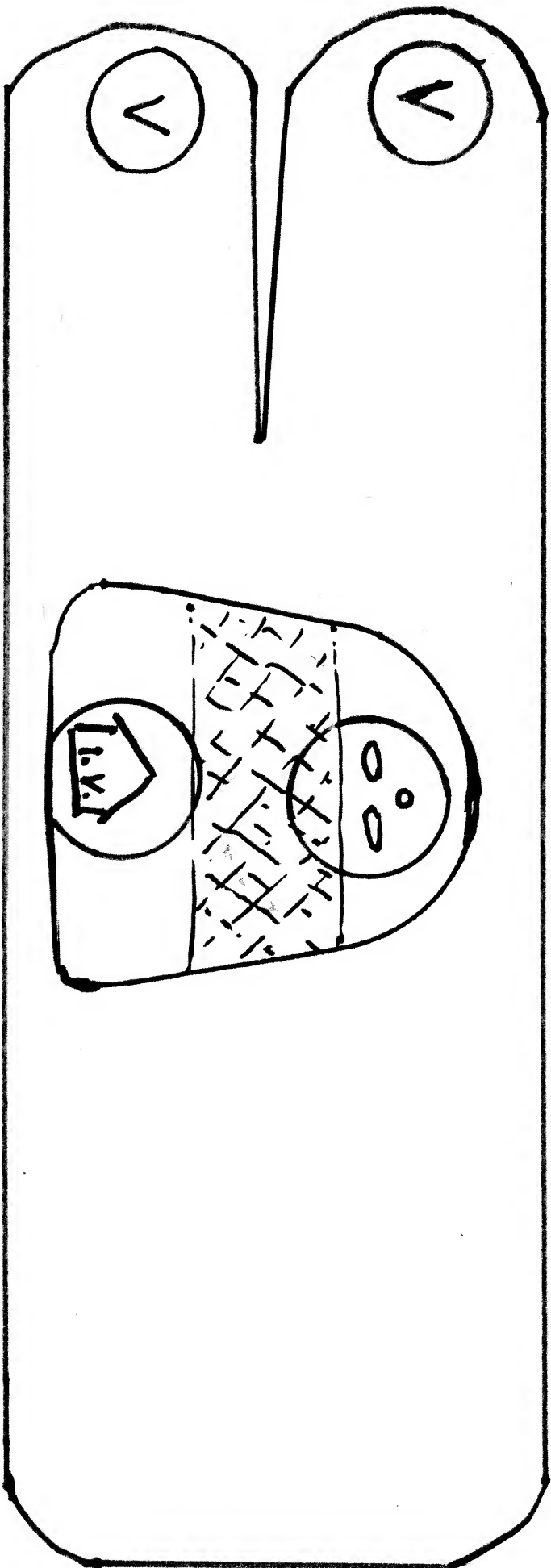
FIG. 2



RIGHT HAND

1-8.2000

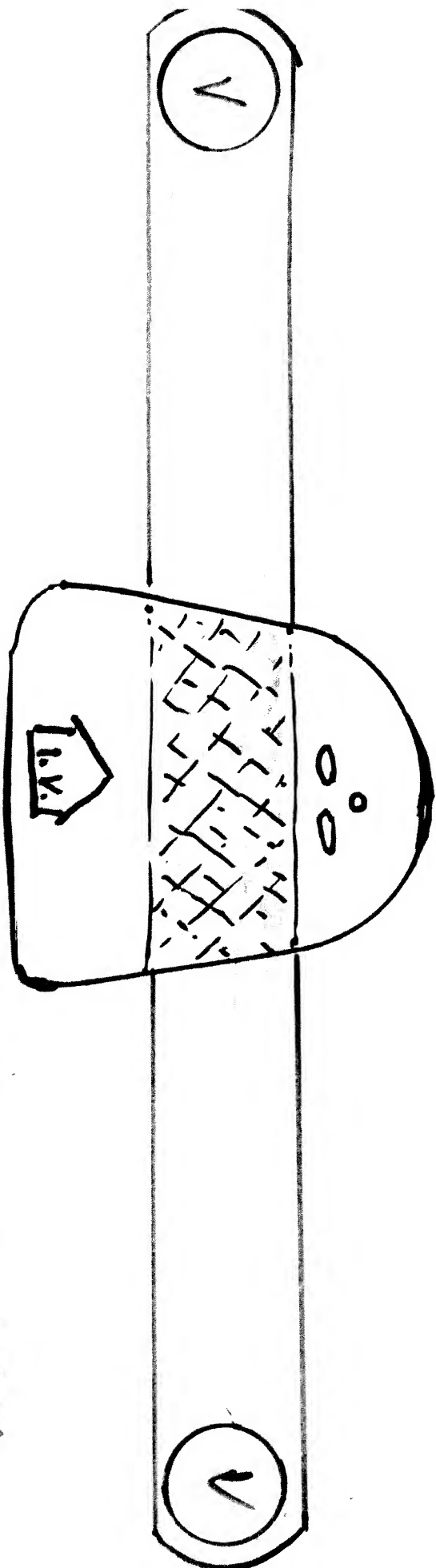
F.4.3



LEFT HAND

1-X-2000

F.S. 4

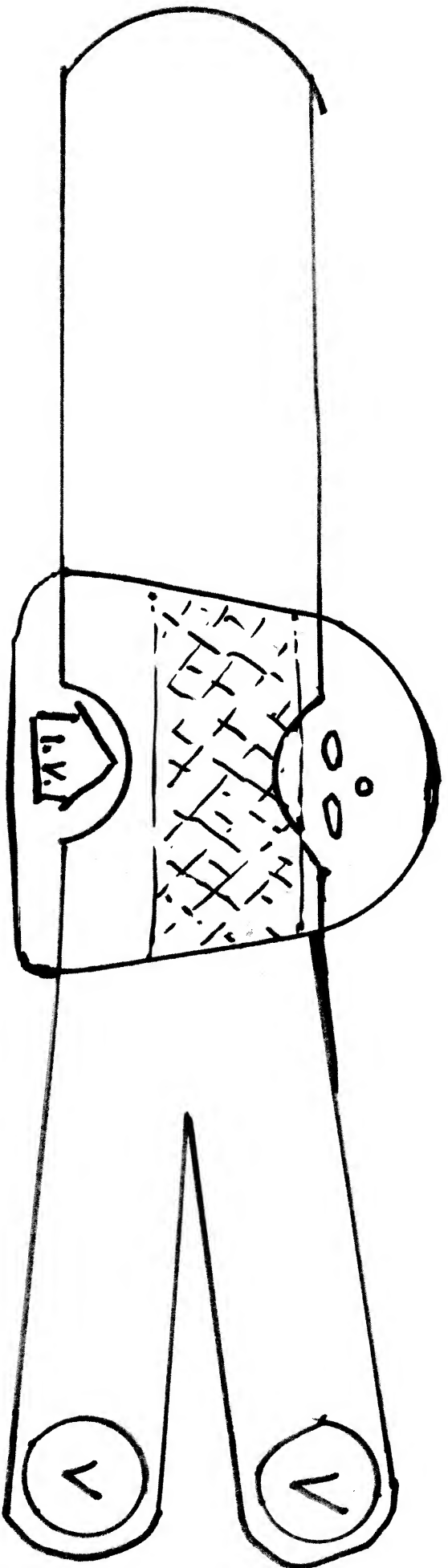


AMBIDEXTROUS HAND OR ARM

UNUSED FASTENER SIMPLY FOLDS UNDER

1-8 2000

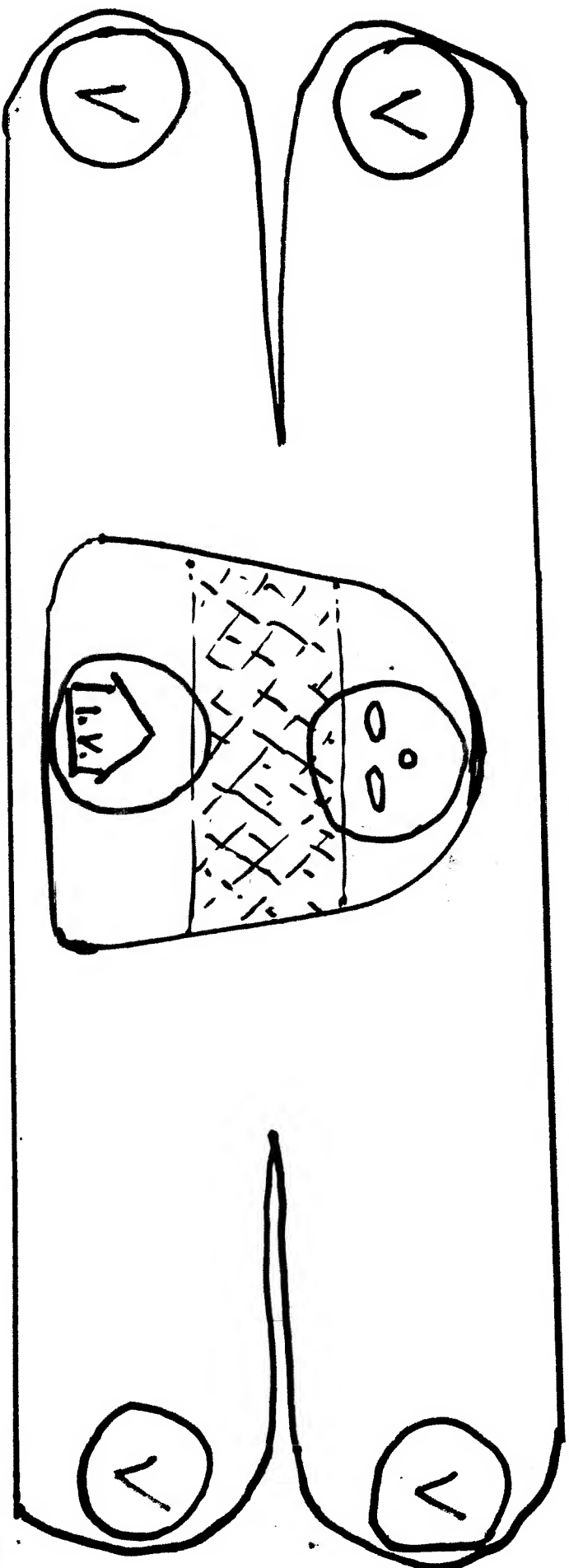
F.G.5



LEFT HAND  
REVERSE ENDS FOR RIGHT HAND

1-8-2000

G. G.



AMBI DEXTROUS HAND OR ARM  
2 CIRCULAR OPENINGS EXPOSE  
VENTILATION AND LOGO

1-8-2000

FIG. 7



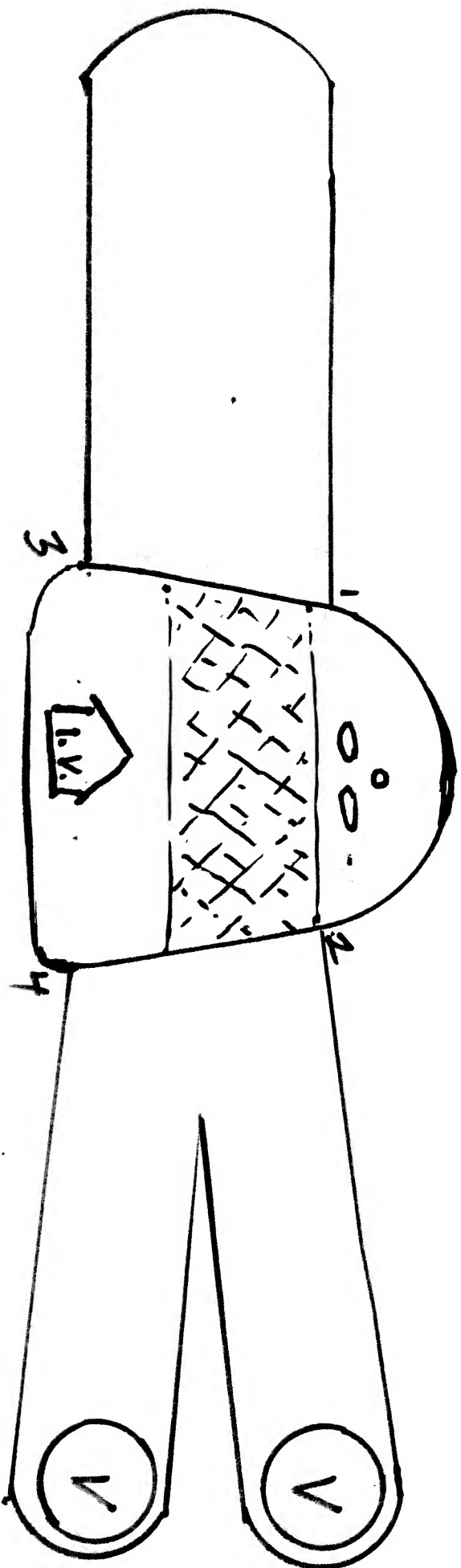
AMBI DEXTROUS HAND

OR ARM

TAPPLESS  
WELOED TO  
EDGES @  
1, 2, 3, 4 OR ALL ALONG BOTH EDGES  
I.V. HOUSE FULLY EXPOSED

1-8-2000

Fig. 8



LEFT HAND

TAPLESS  
WELDED TO

EDGES @

1, 2, 3, 4

OR

ALL

ALONG

BOTH

EDGES

I.V. HOUSE FULLY EXPOSED